

Claims

What is claimed is:

1. A system for use with an implantable medical device (IMD) to selectively
5 promote tissue in-growth, comprising:
a first inner layer of porous Polytetrafluoroethylene (PTFE) adjacent to at least
one surface of the IMD, the first inner layer of porous PTFE having a fibril length
adapted to prevent substantially all tissue in-growth at the at least one surface of the
IMD; and
10 at least one outer layer of porous PTFE adjacent to at least a predetermined
portion of the first inner layer, the outer layer of porous PTFE having a fibril length
adapted to selectively promote tissue in-growth.
2. The system of Claim 1, wherein the first inner layer of porous PTFE is an
15 expanded PTFE (e-PTFE).
3. The system of Claim 2, wherein the at least one outer layer of porous PTFE is an
expanded PTFE (e-PTFE).
- 20 4. The system of Claim 3, wherein the first inner layer of porous PTFE has a fibril
length of less than 10 microns.

5. The system of Claim 4, wherein the at least one outer layer of porous PTFE has a fibril length of between 20 and 50 microns.
6. The system of Claim 5 wherein the first inner layer and the at least one outer layer
5 of porous PTFE are formed of porous PTFE tubing.
7. The system of Claim 6 wherein the porous PTFE tubing is heat-shrink tubing.
8. The system of Claim 5 wherein the first inner layer and the at least one outer layer
10 are formed of tape.
9. The system of Claim 5 wherein the at least one outer layer of porous PTFE is formed by removing a predetermined number of fibrils from the predetermined portion of the first inner layer.
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10. The system of Claim 1 wherein the outer layer is coextensive with the first inner layer.
11. The system of Claim 1, wherein multiple outer layers of porous PTFE are
20 provided, each adjacent to a respective predetermined portion of the first inner layer.

12. The system of Claim 1, wherein the first inner layer and the at least one outer layer of porous PTFE comprise a removable sleeve member provided to be positioned adjacent to at least a portion of the IMD.

5 13. The system of Claim 12, wherein the removable sleeve member is removably fastened to the IMD.

14. The system of Claim 12, wherein the IMD is a medical electrical lead, and wherein the sleeve member is adapted to be positioned adjacent to at least a portion of the
10 medical electrical lead.

15. The system of Claim 1, wherein the IMD is a medical electrical lead having an electrode, the first inner layer is adjacent to at least a portion of the electrode.

15 16. The system of Claim 15, wherein the first inner layer is adjacent to the entire surface of the electrode to prevent substantially all tissue in-growth around the electrode.

17. The system of Claim 16, wherein the electrode is a defibrillation coil, and the first inner layer and the at least one outer layer of porous PTFE are isodiametric with the
20 outer surface of the medical electrical lead.

18. The system of Claim 1, wherein the IMD is a subcutaneous electrode array having multiple electrodes, and wherein each of selected ones of the multiple electrodes is

adjacent to an first inner layer of porous PTFE having a fibril length adapted to prevent substantially all tissue in-growth, and wherein at least one of the first inner layers of porous PTFE has a predetermined portion that is adjacent to an outer layer of porous PTFE having a fibril length adapted to selectively promote tissue in-growth.

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19. The system of Claim 1, and further including a second inner layer of porous PTFE between the IMD and the first inner layer, the second inner layer having a pore size adapted to bleed gas from the surface of the IMD.

10 20. The system of Claim 19, wherein the second inner layer has a pore size of 50 microns or more.

21. The system of Claim 20, wherein the second inner layer has a thickness of 50 microns or more.

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22. A method of selectively promoting tissue in-growth on at least one surface of an implantable medical device (IMD), comprising the methods of:

a.) providing a first layer of a porous Polytetrafluoroethylene (PTFE) having a pore size adapted to prevent substantially all tissue in-growth adjacent to the at least one
20 surface of the IMD; and

b.) providing at least one region of porous PTFE adjacent to the first layer having a pore size adapted to selectively promote tissue in-growth.

23. The method of Claim 22, wherein the providing method includes providing a polymer tubing of porous PTFE having a pore size adapted to selectively promote tissue in-growth to provide the at least one region.

5 24. The method of Claim 23, wherein the polymer tubing is heat-shrinkable tubing, and further including the method of applying heat to the heat-shrinkable tubing to adhere the heat-shrinkable tubing to the first layer.

10 25. The method of Claim 22, wherein the providing method includes the method of selectively removing fibrils from the inner layer to create the at least one region of porous PTFE having a pore size adapted to selectively promote tissue in-growth.

15 26. The method of Claim 22, wherein the providing method includes the method of providing a layer of tape formed of a porous PTFE having a pore size adapted to selectively promote tissue in-growth.

27. The method of Claim 22, wherein method a.) includes the method of forming the first layer of PTFE into a sleeve adapted to be removably positioned adjacent to at least the one surface of the IMD.

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28. The method of Claim 27, and wherein the sleeve is adapted to removably surround a predetermined portion of the IMD.

29. The method of Claim 27, and further including the method of removably positioning the IMD so that the at least one surface of the IMD is adjacent to the sleeve.

30. The method of Claim 29, and further including the method of removably fastening the IMD to the sleeve.

31. The method of Claim 29, and further including the method of implanting the IMD and the sleeve into a body.

32. The method of Claim 31, and further including the method of removing the IMD from sleeve and the body while leaving the sleeve within the body.

33. The method of Claim 32, and further including the method of advancing a second IMD into the sleeve in the body.

34. The method of Claim 22, and further including the method of providing a second layer of porous PTFE between the first layer and the surface of the IMD, the second layer having a pore size adapted to trap gas produced by the delivery of an electrical current by the IMD.

35. The method of Claim 34, wherein the second layer has a pore size of 50 microns or more.

36. A implantable medical device (IMD) to be implanted in a body, including:

enclosure means for enclosure at least a portion of the IMD;

an inner polymer layer adjacent to at least a portion of the enclosure means

formed of a porous Polytetrafluoroethylene (PTFE) having a pore size adapted to prevent

5 substantially all tissue in-growth in the portion of the enclosure means; and

an outer polymer layer adjacent to at least one portion of the inner polymer layer
to selectively promote tissue in-growth when implanted in the body.

37. The IMD of Claim 36, wherein the IMD is a medical electrical lead, and the

10 enclosure means is an outer jacket of the medical electrical lead.

38. The IMD of Claim 36, wherein the inner polymer layer is formed of an expanded
PTFE (e-PTFE).

15 39. The IMD of Claim 38, wherein the outer polymer layer is formed of an expanded
PTFE (e-PTFE).

40. The IMD of Claim 39, wherein the inner polymer layer has a fibril length of less
than 10 microns.

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41. The IMD of Claim 38, wherein the outer polymer layer has a fibril length of
between 20 and 50 microns.

42. The IMD of Claim 41 wherein the inner and outer polymer layers are formed of porous PTFE tubing.

43. The IMD of Claim 42 wherein the porous PTFE tubing is heat-shrink tubing.

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44. The IMD of Claim 41 wherein the inner and outer polymer layers are formed of tape.

45. The IMD of Claim 41 wherein the outer polymer layer is formed by removing a
10 predetermined number of fibrils from the predetermined portion of the inner polymer layer.

46. The IMD of Claim 41 wherein the inner polymer layer is adapted to form a sleeve member to cover the portion of the enclosure means adjacent to the inner polymer layer.
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47. The IMD of Claim 41, wherein the sleeve member is adapted to be removably coupled to the IMD.

48. The IMD of Claim 47, wherein the sleeve member is adapted to surround a
20 predetermined portion of the enclosure means.

49. The IMD of Claim 41, wherein the IMD is a medical electrical lead having an electrode, and the inner polymer layer is substantially adjacent to the electrode.

50. A system for use with an implantable medical device (IMD) to selectively promote tissue in-growth, comprising:

a first layer of porous Polytetrafluoroethylene (PTFE) adjacent to at least one surface of the IMD, the first inner layer of porous PTFE having a fibril length adapted to bleed gas away from the at least one surface of the IMD; and

a second layer of porous PTFE adjacent to at least a predetermined portion of the first layer, the outer layer of porous PTFE having a fibril length adapted to prevent substantially all tissue in-growth.

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51. The system of Claim 50, wherein the first layer of porous PTFE is an expanded PTFE (e-PTFE).

52. The system of Claim 51, wherein the second layer of porous PTFE is an expanded PTFE (e-PTFE).

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53. The system of Claim 52, wherein the first layer of porous PTFE has a fibril length of greater than 50 microns.

54. The system of Claim 53, wherein the second layer of porous PTFE has a fibril length of less than 10 microns.

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55. The system of Claim 54, wherein the first layer and the second layer are formed of porous PTFE tubing.

56. The system of Claim 54, wherein the first layer and the second layer are formed
5 of tape.

57. The system of Claim 50, wherein the IMD includes at least one electrode, and wherein the at least one surface of the IMD is a surface of the at least one electrode.

10 58. The system of Claim 50, and further including a third layer of porous PTFE adjacent to at least a portion of the second layer, the third layer including a pore size adapted to selectively promote tissue in-growth.

59. The system of Claim 58, wherein the pore size of the third layer is between 20
15 and 50 microns.

60. The system of Claim 50, wherein the first layer and the second layer comprise a removable sleeve member provided to be positioned adjacent to at least a portion of the IMD.